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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,875	09/26/2001	Joel F. Habener	17633/1235	9674

29933 7590 09/20/2007
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EXAMINER

BELYAVSKIY, MICHAIL A

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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09/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/963,875

Applicant(s)

HABENER ET AL.

Examiner

Michail A. Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-41, 43, 74, 77-79, 85-107 and 109-111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-41, 43, 74, 77-79, 85-107 and 109-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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RESPONSE TO APPLICANT'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/11/07 has been entered.

2. Claims 39-41, 43, 74, 77-79, 85-107 and 109-111 are pending.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 39-41, 43, 77-79 and 85-107 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 9715310 as is evidenced from the newly cited Hunziker et al., (Biochemical and Biophysical Research Communication, 2000, pages 116-119) for the same reasons set forth in the previous Office Action, mailed on 11/16/06.

Applicant's arguments filed on 07/11/07 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) it is impossible to conclude that instant claims are obvious in view of the WO'97/15310, while claim 1 of Post-filing US Patent 6,436,704 is not. (ii) even if WOP'310 application were to be present, one skill in the art would not have a reasonable

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expectation of success, since the subject matter of the instant claims is unexpected, as is evidence from Declarations under 37 CFR 1.132 by Dr. Habener and by Dr. Weir. In said declarations, Dr. Habener and Dr. Weir expresses their opinions that as of May 27, 2003 a person of skill in the art would not believe in the existence of a population of isolated nestin-positive pancreatic stem cells.

With respect to the issue that "it is impossible to conclude that instant claims are obvious in view of the WO'97/15310, while claim 1 of Post-filing US Patent 6,436,704 is not"

As applicant should be aware, the examiner cannot comment on the validity of a U.S. Patent and should not be asked to do so. Moreover, it is well settled that whether similar claims have been allowed to others is immaterial. See In re Giolito, 530 F.2d 397, 188 USPQ 645 (CCPA 1976) and Ex parte Balzarini 21 USPQ2d 1892, 1897 (BPAI 1991). Moreover, as stated In re Borkowski, 505 F.2d 713, 184 USPQ 29, 33 (CCPA 1974), "The Patent Office must have the flexibility to reconsider and correct prior decisions that may be found to have been in error". In a similar context, the court in Fessenden v. Coe, 38 USPQ 516, 521 (CADC 1938) stated that "[t]wo wrongs cannot make a right."

With regards to the issue raised in Declarations under 37 CFR 1.132 by Dr. Habener and by Dr. Weir that "as of May 27, 2003 a person of skill in the art would not believe in the existence of a population of isolated nestin-positive pancreatic stem cells".

As is evidenced from newly cited Hunziker et al., reference the existence of nestin-positive pancreatic stem cells has been known to one of skill in the art. It is noted that said reference has been published in April of 2000. Applicant attention is respectfully drawn to the discussion section, wherein it is clearly stated that the present study provides evidence of the existence of a subset of nestin-positive pancreatic cells, whether these cells are stem cells is currently being addressed. Thus, it is the Examiner's position that one of skill in the art would expect the existence of a population of isolated nestin-positive pancreatic stem cells at the time the invention was made.

It is noted that said reference is not the prior art reference since it was published after December 1999, however said reference is used as evidence that one of skill in the art would expect the existence of a subpopulation of nestin-positive pancreatic stem cells.

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As has been stated previously, it is the Examiner position that WO'310 teaches an isolated viable nestin-positive human pancreatic stem cells that are not a neural stem cells that can differentiate to form insulin-producing cells. (see entire document, pages 8 ,10, 13 in particular). WO'310 teaches a pharmaceutical composition comprising said cells in cultured media or in PBS, that is a physiologically compatible carrier. (see pages 13 and 14 in particular). WO'310 teaches several methods of isolating pancreatic stem cells comprising steps of removing a pancreatic islet from the donor and separating stem cells from plurality of cells (see overlapping pages 22 -24, in particular). The method of isolating said cells is substantially similar to that used by applicant (see overlapping pages 22-24 in particular). While WO'310 does not specifically teach that these cells are GLP-1R-positive cells, said cells would obviously be GLP-1R-positive cells, since the cell population taught by WO'310 is identical to that claimed in the instant application. It is noted that WO'310 does not explicitly teaches an isolated nestin-positive human pancreatic stem cells, wherein said cells are at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure as claimed . However, at the time the invention was made one skilled in the art would know how to obtained an isolated population of human pancreatic stem cells wherein said cells are at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure as claimed. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, preparing an isolated cell composition that would be at least 30 % or 40% or 60 % or 70 % or 80 % or 85 % or 90 % or 99 % pure involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Moreover, it is noted that Applicant acknowledge that at the time the invention was made one skilled in the art will appreciate that a variety of separation strategies based on immunophenotyping methodologies such as surface coated antibody panning, fluorescent antibody tagging for physical isolation, flow cytometric sorting, immunomagnetic bead and particle selection and counterselection can be used to obtained isolated distinct population of nestin+ cells (see Applicant's argument mailed on 12/27/05, overlapping pages 19-20 in particular).

Claim 43 is included because the claimed functional limitation would be obvious properties of an isolated cells taught by WO'310 because the referenced cells are the same as claimed and would obviously be able to differentiates to insulin-producing cells. Said insulin -producing cells are the only beta cells to which nestin-positive human pancreatic stem cells can differentiate in the absence of evidence of structural difference.

Claims 77-79 and 105-107 are included because the instant claims are drawn to a product, i.e. to an isolated nestin-positive human pancreatic stem cells. Patentability of the product, i.e. isolated, nestin-positive stem cells does not depends on the method of production or a source from which said cells were isolated in the absence of evidence of structural difference. In *re Thrope*, 227 USPQ 964,966 (Fed. Cir. 1985). See MPEP 2113.

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 74 and 109-11 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 9715310 for the same reasons set forth in the previous Office Action, mailed on 11/16/06.

Applicant's arguments filed on 07/11/07 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) it is impossible to conclude that instant claims lack novelty in view of the WO'97/15310, while claim 1 of Post-filing US Patent 6,436,704 is not.

As has been discussed supra, the examiner cannot comment on the validity of a U.S. Patent and should not asked to do so. Moreover, it is well settled that whether similar claims have been allowed to others is immaterial. See In re Giolito, 530 F.2d 397, 188 USPQ 645 (CCPA 1976) and Ex parte Balzarini 21 USPQ2d 1892, 1897 (BPAI 1991). Moreover, as stated In re Borkowski, 505 F.2d 713, 184 USPQ29,33 (CCPA 1974), "The Patent Office must have the flexibility to reconsider and correct prior decisions that may find to have been in error". In a similar context, the court in Fessenden v. Coe, 38 USPQ 516,521 (CADC 1938) stated that "[t]wo wrongs cannot make a right."

WO'310 teaches an isolated viable nestin-positive human pancreatic stem cells that are not a neural stem cells that can differentiate to form insulin-producing cells. (see entire document, pages 8,10, 13 in particular). WO'310 teaches a pharmaceutical composition comprising said cells in cultured media or in PBS, that is a physiologically compatible carrier. (see pages 13 and 14 in particular). WO'310 teaches several methods of isolating pancreatic stem cells comprising steps of removing a pancreatic islet from the donor and separating stem cells from plurality of cells (see overlapping pages 22 -24, in particular). The method of isolating said cells is substantially similar to that used by applicant (see overlapping pages 22-24 in particular). While WO'310 does not specifically teach that these cells are GLP-1R-positive cells, said cells would obviously be GLP-1R-positive cells, since the cell population taught by WO'310 is identical to that claimed in the instant application. Mere recognition of latent properties in the prior art (i.e. nestin-positive cell is also GLP-1R positive) does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979).

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Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Since the office does not have a laboratory to test the reference isolated nestin-positive human pancreatic stem cells, it is applicant's burden to show that the reference nestin-positive human pancreatic stem cells do not have the functional limitation as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

7. No claim is allowed

9. This is a RCE of applicant's earlier Application No. 09963875 . All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAIL BELYAVSKIY, PH.D.
PATENT EXAMINER

09/14/07